Hemezyme
GENUINE QUALITY, RELIABLE RESULTS.

BILIRUBIN TOTAL & DIRECT

(SINGLE REAGENT - MODIFIED BERGH & MULLER METHOD)

INTENDED USE:

Reagent kit for the quantitative determination of Total and Direct Bilirubin in serum.

CLINICAL SIGNIFICANCE:

Approximately 80-85% of the bilirubin produced is derived from the heme moiety of the hemoglobin released from aging erythrocytes in the reticuloendothelial cells. Bilirubin bound to albumin is transported into the liver where it is rapidly conjugated with glucuronide to increase its solubility. Then it is excreted into biliary canaliculi and hydrolyzed in the gastrointestinal tract. Unconjugated bilirubin serum concentration increases in case of overproduction of bilirubin (acute or chronic hemolytic anemias) and in case of disorders of bilirubin metabolism and transport defects (impaired uptake by liver cells: Gilbert's syndrome; defects in the conjugation reaction: Crigler-Najjar syndrome). Reduced excretion (hepatocellular damage hepatitis, cirrhosis...; Dubin-Johnson and Rotor syndrome) and obstruction to the flow of bile (most often produced by gallstones or by tumors) induce an important elevation of conjugated bilirubin and in a minor extent an increase of unconjugated bilirubin

REAGENT COMPOSTION:

Reagent T1: Total Bilirubin reagent
Reagent D1: Direct Bilirubin reagent

MATERIALS REQUIRED BUT NOT PROVIDED:

-Clean & Dry Glassware.
-Micropipettes & Tips.
-Colorimeter or Bio-Chemistry Analyzer.

SAMPLES:

Serum free of hemolysis. Heparinized plasma.
Care must be taken to fill heparinized tubes according to the manufacturer's instructions. An insufficient filling may lead to erroneous results. Protect the samples from light before and during the analysis.

STABILITY OF REAGENT:

When stored tightly closed at 2° TO 8° C protected from light and contaminations prevented during their use; reagents are stable up to the expiry date stated on the label.

WORKING REAGENT:

The Reagent is ready for use.

LINEARITY

Reagent is Linear up to 20 mg/dl.

Dilute the sample appropriately and re-assay if Total or Direct Bilirubin concentration exceeds 20 mg/dl. Multiply the result with the dilution factor.

GENERAL SYSTEM PARAMETERS:

REACTION TYPE	End Point (Increasing)
PRIMARY WAVE LENGTH	546 nm
SECONDARY WAVE LENGTH	630 nm
LIGHT PATH	1 cm
REACTION TEMPERATURE	37°c
BLANK / ZERO SETTING	Reagent Blank
REAGENT VOLUME	1 ml
SAMPLE VOLUME	50 µl
INCUBATION TIME	5 Minutes
TOTAL BILIRUBIN FACTOR	30
DIRECT BILIRUBIN FACTOR	15
LINEARITY	20 mg/dl

ASSAY PROCEDURE:

1. Take two clean, dry test tubes labeled B (blank), T (test).

2. Set the instrument to zero with the blank, then aspirate the sample one by one to read the results.

Total Bilirubin:

	BLANK	TEST
T. BILIRUBIN (T1)	1ml	1ml
SAMPLE		50 µl

Direct Bilirubin:

	BLANK	TEST
D. BILIRUBIN (D1)	1ml	1ml
SAMPLE		50 µl

Mix and read the absorbance of the tests against their respective reagent blanks after a 5-minutes incubation at 37°C.

CALCULATIONS:

Total Bilirubin (mg/dl) = (Abs. Test-Abs. Sample Blank) X 30
Direct Bilirubin (mg/dl) = (Abs. Test-Abs. Sample Blank) X 15

REFERENCE NORMAL VALUE:

Total Bilirubin: (Adults and children over 10 days) 0.3-1.2 mg/dl
Direct Bilirubin: <0.2 mg/dl

QUALITY CONTROL:

For accuracy it is necessary to run known controls with every assay.

BIBLIOGRAPHY:

Tietz, N.W., Clinical guide to laboratory tests. 3rd Ed., (W.B. Saunders eds. Philadelphia USA), (1995), 90. Vassault, A., et al. Protocole de validation de techniques. (Document B, stade 3), Ann. Biol. Clin., (1986), 44, 686.

PACK SIZE: HBS100 4x25ml

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HBS100 4 x25ml (RT-2 X 25ml, RD- 2 X 25ml)

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